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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,650	05/25/2006	Svend Erik Borgesen	BORGESEN5A	5770

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,650	BORGESEN, SVEND ERIK	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,20,24,26-38,48 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,20,24,26-38,48 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5, 24, 26-31, 37, 38, 48, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,283,934 to Borgesen.

In the specification and figures, Borgesen discloses the method as claimed by applicant.

With regard to claims 1 and 37, Borgesen discloses the apparatus substantially as claimed by applicant. In particular, Borgesen discloses a system for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, particularly, the saggital sinus (see column 1, lines 10-17, column 2, lines 58-65). The shunt system comprises:

a. a shunt body 12 allowing fluid communication between a ventricle 14 and saggital sinus 15, wherein the shunt body comprises or flow restricting

component 3 capable of maintaining a constant resistance to fluid flow (see FIGS 6, 8, column 4, lines 20-23, column 6, column 7, line 65 to column 8, line 25),

b. brain ventricle catheter 13 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least FIG 8)

c. a sinus catheter (seen generally at reference numeral 7 in FIG 2, unlabeled in FIG 8) connected to the shunt body (see FIG 8), wherein the sinus catheter is capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor.

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material (see, generally, column 6). Applicant claims that the biocompatible material comprises an inert surface preventing biological material from maintaining longer lasting contact with the inert surface. However, applicant fails to define such what comprises such an inert surface in the specification, defining only the composition of the hemocompatible material with charged species thereupon. Since Applicant discloses that the apparatus may be made of various inert biocompatible materials (see applicant's 2007/0112291, paragraph 0091), it is the position of the Examiner that Borgensen's disclosure of the same materials meets the limitations of the claim.

With regard to claims 2, 5, 24, Borgesen discloses that the flow restricting structure and the tubes provide a resistance to flow of about 8 to 12 mm Hg/mL/min, which includes values just less than 8 (see column 6, lines 42-45). It is the position of

the Examiner that the flow restricting component is *capable* of providing the flow resistance claimed by applicant.

With regard to claim 26, Borgesen discloses that the flow restricting passage comprises a tubular structure (see column 6, line 42).

With regard to claims 27-30, Borgesen discloses that the internal radius of the flow-restricting passage may be 0.15mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see column 6, lines 42-50).

With regard to claim 31, Borgesen discloses that the apparatus may comprise a check valve 8 (see column 8, line 18).

With regard to claim 38, Borgesen discloses that the shunt body comprises a body and antechamber 2 made of the claimed materials (see column 6, lines 27-42). The apparatus comprises a tapering tip 7, 7' to which a catheter can be secured, wherein the antechamber 2 is connected to the tubular flow restricting element 3 so that the chamber forms an inlet to the restricting component, wherein the check valve (represented as ball 4) is arranged between the antechamber and the flow restricting element, wherein the apparatus comprises the drain and catheters claimed by applicant (see FIGS 6-8 and accompanying text).

With regard to claim 48, Borgesen discloses a method for implanting the claimed shunt wherein the shunt is placed subcutaneously on the top of the calvarium, inserting the catheters, connecting the catheters, and allowing fluidic communication between the catheters (see column 6, lines 12-23, column 8, line 59 to column 10 line 5).

With regard to claim 60, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see column 8, lines 27-47).

4. In addition to the rejection presented above, claims 1, 10, and 34-47, are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0045847 to Borgesen.

With regard to claims 1 and 37, Borgesen discloses a system for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, which may comprise the transverse sinus (see paragraphs 0002, 0003, 0058). The shunt system comprises:

a. a shunt body 10 allowing fluid communication between a ventricle 21 and ventricular sinus, wherein the shunt body comprises a flow restricting component 16 capable of maintaining a constant resistance to flow (see FIG 8, paragraph 0052),

b. brain ventricle catheter 15 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least paragraph 0053)

c. a sinus catheter 18 (se at least paragraph 0055) connected to the shunt body, wherein the sinus catheter is capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor.

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material (see, generally, paragraph 0052). Applicant claims that the biocompatible material comprises an inert surface preventing biological material from maintaining longer lasting contact with the inert surface. However, applicant fails to define such what comprises such an inert surface in the specification, defining only the composition of the hemocompatible material with charged species thereupon. Since Applicant discloses that the apparatus may be made of various inert biocompatible materials (see applicant's 2007/0112291, paragraph 0091), it is the position of the Examiner that Borgensen's disclosure of the same materials meets the limitations of the claim.

With regard to claims 2, 5, 20, and 24, Borgesen discloses that the flow restricting structure and the tubes provide a resistance to flow of less than 8 mm Hg/mL/min, preferably 4-6 mm Hg/mL/min (see paragraph 0031).

With regard to claim 26, Borgesen discloses that the flow restricting passage comprises a tubular structure (see paragraph 0026).

With regard to claims 27-30, Borgesen discloses that the internal radius of the flow-restricting passage may be less than 0.20mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see paragraphs 0033, 0035, 0036).

With regard to claims 31-36, Borgesen discloses that the apparatus may comprise a mitral silicone check valve wherein the check valve provides no fluid resistance to the CSF, rendering fluid flow resistance independent of the check valve

with the check valve operating independently of the fluid pressure threshold (see paragraph 0040).

With regard to claim 38, Borgesen discloses that the shunt body comprises a body and antechamber 11 with opposite flat walls 12 made of the claimed materials (see paragraph 0052). The top walls of the chamber end in tip 14, to which a ventricular catheter 15 may be attached. The distal end of chamber 11 has an inlet to tubular flow restriction 16 with a check valve 17 placed therebetween. Fluidic connection to the sinus system is provided by drain 18 and fluidic connection to the brain ventricle is provided by ventricle catheter 15 (see paragraph 0052).

With regard to claim 48, Borgesen discloses a method for implanting the claimed shunt wherein the shunt is placed subcutaneously on the top of the calvarium, inserting the catheters, connecting the catheters, and allowing fluidic communication between the catheters (see paragraph 0031).

With regard to claim 60, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see paragraph 0032).

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,980,480 Rubinstein et al

i. Method of treating Alzheimer's with CSF shunting

b. US 2002/0026138 Cowan et al

ii. CSF shunt coated to prevent adhesion

c. US 6,234,991 Gorsuch

iii. Indwelling catheter coated with polyethylene glycol to reduce adhesions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
1 May 2008